

### **REMARKS**

This replacement amendment is being filed in response to the Notice of Non-Compliant Amendment mailed April 16, 2010, in order to correct several claim status identifiers in the amendment filed March 29, 2010. The Applicants thank the Examiner for the careful attention given the application in the previous Office Action. The Applicants would also like to thank the Examiner and Mr. Rodriguez for the courtesies extended to the undersigned and Dr. Whirley during the telephonic interview on March 11, 2010. During the interview, claim 1 and claims having similar limitations were discussed in view of the Witcher and Chong references. It was agreed during the interview that the amendment made to claim 1 and similar independent claims, as indicated above, would clarify the language of the claims so as to overcome Chong.

Currently, claims 1-12, 14-27, 29-39, 41-42, 54-65, 67-81, 83-94, 96-98 and 112-125 are pending in the application and stand rejected. All rejections are respectfully traversed in their entirety, including all reasons and rationale for the rejections. Applicants have amended the claims as indicated above in order to clarify the language of the claims. The amendments to the claims are fully supported by the specification as filed, no new matter has been added. The claim amendments and new claims herein are introduced solely to expedite prosecution without prejudice or disclaimer of any previously claimed subject matter. Applicant has not dedicated or abandoned any unclaimed subject matter and has not acquiesced to any rejections or objections made by the Office by introducing the amendments and new claims herein. Applicant expressly reserves the right to pursue prosecution of any presently excluded or cancelled subject matter or embodiments in one or more future continuing patent applications.

#### **35 USC section 103(a)**

Claims 1-3, 5-7, 9-10, 14, 15, 112-113, 16-18, 20-22, 24-25, 29-31, 114-115, 31-37, 41, 42, 116-117, 54, 56, 58-60, 62-63, 67-69, 118, 70, 72, 74-76, 78-79, 83-85, 124-125, 86, 88-92, 96-98, 119, 124 and 125 stand rejected under 35 U.S.C. section 103(a) as being unpatentable over "Simulation of in vivo loading conditions of nitinol

vascular stent structures" by F.D. Witcher (Witcher) in view of "A Prototype Simulator for Endovascular Repair of Abdominal Aortic Aneurysms" by C.K. Chong et al. (Chong). The rejection is respectfully traversed.

Claim 1 as currently pending is directed to:

A computer system including at least one processor and memory for analyzing medical devices comprising:

- a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature(s) of at least one vascular system and generates a geometric model of said anatomical feature(s);

- a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and generates a finite element model representing both of said geometric model of said anatomical feature(s) and said geometric model of said medical device; and

- a stress/strain/deformation analyzer that receives said finite element model, material properties of said anatomical feature(s) and said medical device, load data on said anatomical feature(s) and/or said medical device and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the anatomical feature(s) to determine the predicted stresses, strains, and deformations of said medical device due to the interaction of the medical device with the anatomical feature(s).

Applicants respectfully suggest that even if the two primary references of Witcher and Chong are combined, they do not teach or suggest all elements of claim 1. Claim 1 includes a mesh generator that receives a geometric model of anatomical feature(s) and a geometric model of a medical device, and generates a finite element model representing both of said geometric model of said anatomical feature(s) and said geometric model of said medical device.

Neither Witcher nor Chong teach or suggest a mesh generator that generates a single finite element model representing both an anatomical feature and medical device

together. Witcher teaches a rudimentary finite element model of a stent, but not a finite element model of an anatomical feature. Chong teaches a surface triangulation of an arterial wall for use in machining or surface milling acrylic plastic blocks to create a physical model of an aneurysm for bench test or laboratory test purposes. However, Chong does not teach a finite element model. In addition, the data produced by the methods of Chong would not be suitable for analysis by finite element analyzer. Therefore, even if combined, the references fail to teach or suggest the claimed limitations.

The previous Office Action suggests that "Witcher teaches a generated geometric model of said anatomical feature(s) and a mesh model of a medical device" with reference to Figs. 3 and 5 and page 1009 of Witcher. However, Fig. 3 of Witcher is directed to a stent geometry only and Fig. 5 of Witcher shows pressure load application to a beam. Applicants are unable to identify any teaching or suggestion of a geometric model of an anatomical feature.

The previous Office Action also suggests that "Chong teaches...[a] mesh generator that receives said geometric model of said anatomical features and generates a finite element model or mesh representing said anatomical features" referencing the captions and Figs. 1 and 3 and page 331 of Chong. The previous Office Action also states that "Chong teaches an explicit finite element model of the abdominal aortic aneurysm" referencing Chong at Figs. 1 and 2. However, as discussed above, Chong does not teach a finite element model. Chong appears to teach a three dimensional surface triangulation model for machining purposes that would not be suitable for finite element analysis.

Claim 1 includes a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, load data on said anatomical feature(s) and/or said medical device and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the anatomical feature(s) to determine the predicted stresses, strains, and deformations of said medical device due to the interaction of the medical device with the anatomical feature(s).

Neither Witcher nor Chong teach a stress/strain/deformation analyzer that simulates an interaction between an anatomical feature and a medical device using a mesh that includes both a medical device and the anatomical feature. Witcher simulates the response of a 120 element subdivision of a stent based on a vector component of a pressure load. See p. 1009, second paragraph. Witcher does not teach simulation using a mesh that includes both a medical device and an anatomical feature. Chong does not teach simulation by an analyzer of any type.

In addition, Witcher does not teach simulation of an interaction between an anatomical feature and a medical device over at least one dynamic expansion and contraction cycle. Witcher states on page 1009 that "[t]he loading conditions for this analysis therefore consider only the preload and pulsatile radial forces on the structure". However, though these forces may have been "considered", it is not clear that the pulsatile radial forces were simulated. Furthermore, a force may be pulsatile and still not include one dynamic expansion and contraction cycle

In view of the foregoing, the combination of Witcher and Chong does not teach all limitations of claim 1, and claim 1 is allowable over the cited combination. Claims 2, 3, 5-7, 9, 10, 14-18, 20-22, 24, 25, 29, 30-37, 41, 42, 54, 56, 58-60, 62, 63, 67-70, 72, 74-76, 78, 79, 83-86, 88-92, 96-98, 112-119, 124, 125 include the same or similar limitations as those discussed above with regard to claim 1 and Applicants repeat the applicable portions of the remarks above. As such, these claims are allowable over Witcher and Chong for at least the same reasons as those discussed above with regard to claim 1.

Claims 4, 19, 57 and 73 stand rejected under 35 U.S.C. section 103(a) as being unpatentable over Witcher in view of Chong as discussed in the previous Office Action with regard to claims 1, 16, 54 and 70, and further in view of U.S. Patent No. 5,880,976 to DiGioia III et al. (DiGioia). The rejection is respectfully traversed.

Claims 4, 19, 57 and 73 depend from claims 1, 16, 54 and 70, respectively, and are allowable over Witcher and Chong for at least the reasons discussed above with regard to these respective claims. In addition, claim 4 recites a geometry generator that

receives three-dimensional volumetric data acquired via MRI of at least one anatomical feature(s) of at least one vascular system and generates a geometric model of said anatomical feature(s). As discussed above, Whitcher does not teach or suggest a geometry generator for generation of a geometric model of an anatomical feature. Also, neither Chong nor DiGioia teach or suggest such a geometry generator. As such, DiGioia fails to cure the deficiencies of Whitcher and Chong and claim 4 is allowable over the cited combination of references for at least this reason as well. Although it appears that DiGioia discusses the use of tomographic data obtained from MRI for producing a model of a bone joint, there is no teaching of acquiring three-dimensional volumetric data of an anatomical feature of a vascular system. Claim 4 is therefore allowable over the cited combination. Claims 19, 57 and 73 include the same or similar limitation to that of claim 4 and are also allowable over the cited combination of references for at least the same reason.

Claims 8, 23, 61 and 77 stand rejected under 35 U.S.C. section 103(a) as being unpatentable over Whitcher in view of Chong and further in view of "Automated Mesh Generation of an Arterial Bifurcation Based upon In Vivo MR Images" by Seung Lee et al. (Lee). Applicants respectfully traverse the rejection.

Claims 8, 23, 61 and 77 depend from claims 1, 16, 54 and 70, respectively, and are allowable over Whitcher and Chong for at least the reasons discussed above with regard to these claims. Lee fails to cure the deficiencies of Whitcher and Chong and the claims are allowable over this cited combination as well. Lee appears to be directed to the creation of a model of a lumen, not an anatomical feature, for numerical flow simulation. In addition, Lee does not appear to teach a software application which generates surface points from three dimensional volumetric data which are then converted into stereolithography, slice files, IGES files or a combination thereof as recited in claims 8, 23, 61 and 77. The claims are allowable over the cited combination for this reason also.

Claims 11-12, 26-27, 38-39, 64-65, 80-81 and 93-94 stand rejected under 35 U.S.C. section 103(a) as being unpatentable over Whitcher in view of Chong and further in view of "Computational Mechanics Moves Ahead" by Peter J. Raboin (Raboin). As

discussed above, the combination of Whitcher and Chong fail to teach all elements of claims 1, 16, 31, 54, 70 and 86 from which claims 11-12, 26-27, 38-39, 64-65, 80-81 and 93-94 depend, respectively. Raboin fails to cure the deficiencies of these references. Raboin appears to be directed to a general discussion of improvements to finite element solutions and generally discusses modeling of hip joint implants. However, Raboin does not teach or suggest simulating an interaction between anatomical feature(s) and a medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data. As such, Raboin fails to cure the deficiencies of Whitcher and Chong and claims 11-12, 26-27, 38-39, 64-65, 80-81 and 93-94 are allowable over the cited references.

Claims 55, 71, 87, and 120-123 stand rejected under 35 U.S.C. section 103(a) as being unpatentable over Whitcher in view of Chong and further in view of "Failure of All-ceramic Fixed Partial Dentures in vitro and in vivo: Analysis and Modeling" by J.R. Kelly, J.A. Tesk, and J.A. Sorensen (Sorensen). As discussed above, the combination of Whitcher and Chong fails to teach all elements of claims 54, 70 and 86 from which claims 55, 71, 87, and 120-123 depend, respectively. Sorensen fails to cure the deficiencies of Whitcher and Chong, thus the claims are also allowable over this cited combination as well.

In addition, regarding claims 120-123, Applicants repeat the previous remarks in that it is not clear that Sorensen discloses simulating stresses/strains/deformations to a point of failure. Although Weibull failure probability calculations, incorporating FEA stress profiles are discussed, simulation to a point of failure is not. In addition, the identification of the location of maximum principal tensile stresses and the correlation of such locations with fractographic observations does not require simulation to a point of failure. Furthermore, claim 122 is directed to the method of claim 120 further including varying one or more in vitro failure mode test parameters based on an additional step of comparing simulation data generated by said step of simulating stresses, strains, and deformations imposed on said candidate medical device design by said load data representing said anatomical feature and additional simulation data generated by said

step of simulating stresses, strains, and deformations imposed on said candidate medical device design by said load data in said in vitro failure mode test. Claim 123 includes the limitations of claim 122 and recites that the one or more in vitro failure mode test parameters include test frequency. These limitations are not taught or suggested by Sorensen, Whitchee or Chong, and the claims are allowable over the cited references for at least these reasons as well.

### **CONCLUSIONS**

In view of the foregoing, Applicants respectfully submit that the Office can properly withdraw the outstanding claim rejections and that the pending claims herein are in condition for allowance. Applicants therefore respectfully request that the Office withdraw the outstanding claim rejections and issue a notice of allowance.

In the unlikely event a fee calculation document or other pertinent document is separated from this submission and the Office determines that an extension and/or other relief is required, Applicant petitions for any required relief, including extensions of time, and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **50-2949**.

Respectfully submitted,

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